CENTER FOR DRUG EVALUATION AND RESEARCH

Application Number 74-771

FINAL PRINTED LABELING

60 SINGLE DOSE PACKETS

NDC 0172-2830-90

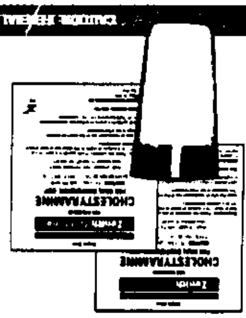
Zenith Goldline

CHOLESTYRAMINE FOR ORAL SUSPENSION, USP

4 grams cholestyramine resin, USP, per packet*

Usual Dosage: See package insert. Store between 15° and 30°C (59° and 86°F).

*Each packet contains 4 grams of anhydrous cholestyramine in 9 grams of Cholestyramine for Oral Suspension.



PREPARATION OF CHOLESTYRAMINE FOR ORAL SUSPENSION, USP

Cholestyramine for oral suspension, USP – your choice of noncarbonated beverage

1. Pour contents of one Cholestyramine for Oral Suspension, USP packet into a glass or cup.

2. Add 2 to 6 ounces of your favorite beverage (orange juice is a popular choice) and stir vigorously.

3. Add more ... to taste and stir again.

Zenith Goldline

PHARMACY LABEL

- Maintain diet and exercise as directed by your physician.
- Find a suitable time to take your medication daily (it may be useful to take Cholestyramine for Oral Suspension, USP with meals).
- Cholestyramine For Oral Suspension, USP can be mixed and refrigerated for three days (remember to mix well each time before drinking or eating).
- Cholestyramine For Oral Suspension, USP can also be easily mixed in a blender.
- Ask your pharmacist or physician for new and different ways to prepare Cholestyramine For Oral Suspension, USP.
- **Always mix Cholestyramine For Oral Suspension, USP with water, or the beverage of your choice, or other highly fluid foods or fruits before using.**
- Usual Dosage: See package insert for dosage information.

WARNING: Keep this and all medication out of the reach of children.

Cholestyramine For Oral Suspension, USP is manufactured under strict quality control standards by Zenith Goldline Pharmaceuticals, Inc., a worldwide leader in healthcare.

CARTON
27672/
PRINT S

60 SINGLE DOSE PACKETS

NDC 0172-

Zenith Goldline

PREPARATION OF CHOLESTYRAMINE FOR ORAL SUSPENSION, USP:
Cholestyramine for oral suspension, USP can be mixed with your choice of noncarbonated beverage.

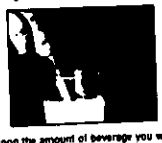
1. Pour contents of one Cholestyramine for Oral Suspension, USP packet into a glass or cup.

2. Add 2 to 6 ounces of your favorite beverage (orange juice is a popular choice) and stir vigorously.

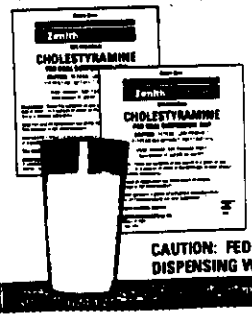
3. Add at least 2-4 more ounces of beverage to suit individual taste and stir vigorously again.

4. The slightly-textured Cholestyramine for Oral Suspension, USP mixture is now ready to drink.






NOTE: More than one packet can be mixed at one time depending upon the amount of beverage you wish to consume when taking your Cholestyramine for Oral Suspension, USP. You may mix to suit your individual taste.



CHOLESTYRAMIN
FOR ORAL SUSPENSION, US

4 grams cholestyramine resin, USP, per packe

This product co

Usual Dosage: See package insert. Store between 15° and 30°C (5
*Each packet contains 4 grams of anhydrous cholestyramine r
of Cholestyramine for Oral Suspension.

CAUTION: FEDERAL LAW PROHIBITS DISPENSING WITHOUT PRESCRIPTION.

ZENITH GOLDLINE PHARMACEUTIC
Ft Lauderdale,

CARTON LABEL
27672A.EPS
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NDC 0172-2830-90

ith Goldline

HOLESTYRAMINE
R ORAL SUSPENSION, USP

rams cholestyramine resin, USP, per packet*

This product contains sucrose.

Dosage: See package insert. Store between 15° and 30°C (59° and 86°F).
ch packet contains 4 grams of anhydrous cholestyramine in 9 grams of Cholestyramine for Oral Suspension.

W PROHIBITS PRESCRIPTION.

ZENITH GOLDLINE PHARMACEUTICALS INC
Ft. Lauderdale, FL 33309

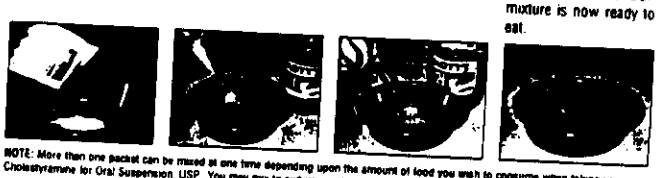
PREPARATION OF CHOLESTYRAMINE FOR ORAL SUSPENSION, USP:
Cholestyramine for oral suspension, USP can easily be mixed with highly fluid foods or fruits.

1. Pour contents of one Cholestyramine for Oral Suspension, USP packet in bowl

2. Add at least 6 ounces of applesauce or other food.

3. Mix well.

4. The slightly-textured Cholestyramine for Oral Suspension, USP mixture is now ready to eat.



NOTE: More than one packet can be mixed at one time depending upon the amount of food you wish to consume when taking your Cholestyramine for Oral Suspension, USP. You may mix to suit your individual taste

CHOLESTYRAMINE
FOR ORAL SUSPENSION, USP
1001366 Revised 9705

APPROVED

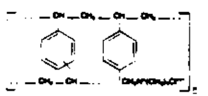
CHOLESTYRAMINE

FOR ORAL SUSPENSION, USP

CAUTION: FEDERAL LAW PROHIBITS DISPENSING WITHOUT PRESCRIPTION

DESCRIPTION

Cholestyramine for Oral Suspension, USP, the chloride salt of a basic anion exchange resin, a cholesterol lowering agent, is intended for oral administration. Cholestyramine resin is quite hydrophilic, but insoluble in water. The cholestyramine resin in this product is not absorbed from the digestive tract. Nine grams of cholestyramine for oral suspension contain 4 grams of anhydrous cholestyramine resin. It is represented by the following structural formula:



Representation of structure of main polymeric groups

Cholestyramine for Oral Suspension USP contains the following inactive ingredients: acacia NF, citric acid (anhydrous) USP, natural lemon flavor, sucrose NF (Bakers special), xanthan gum NF.

CLINICAL PHARMACOLOGY

Cholesterol is probably the sole precursor of bile acids. During normal digestion, bile acids are secreted into the intestines. A major portion of the bile acids is absorbed from the intestinal tract and returned to the liver via the enterohepatic circulation. Only very small amounts of bile acids are found in normal serum.

Cholestyramine resin absorbs and combines with the bile acids in the intestine to form an insoluble complex which is excreted in the feces. This results in a partial removal of bile acids from the enterohepatic circulation by preventing their absorption.

The increased fecal loss of bile acids due to cholestyramine resin, USP administration leads to an increased oxidation of cholesterol to bile acids, a decrease in beta lipoprotein or low density lipoprotein plasma levels and a decrease in serum cholesterol levels. Although in man, cholestyramine resin, USP produces an increase in hepatic synthesis of cholesterol, plasma cholesterol levels fall.

In patients with partial biliary obstruction, the reduction of serum bile acid levels by cholestyramine resin, USP re-

increased oxidation of cholesterol to bile acids, a decrease in beta lipoprotein or low density lipoprotein plasma levels and a decrease in serum cholesterol levels. Although in man, cholestyramine resin, USP produces an increase in hepatic synthesis of cholesterol, plasma cholesterol levels fall.

In patients with partial biliary obstruction, the reduction of serum bile acid levels by cholestyramine resin, USP reduces excess bile acids deposited in the dermal tissue with resultant decreases in pruritus.

Clinical Studies

In a large, placebo-controlled, multi-clinic study, LRC-CPPT[1], hypercholesterolemic subjects treated with cholestyramine resin had mean reductions in total and low-density lipoprotein cholesterol (LDL-C) which exceeded those for diet and placebo treatment by 7.2% and 10.4%, respectively. Over the seven-year study period the cholestyramine resin group experienced a 19% reduction (relative to the incidence in the placebo group) in the combined rate of coronary heart disease death plus non-fatal myocardial infarction (cumulative incidences of 7% cholestyramine resin and 8.6% placebo). The subjects included in the study were men aged 35 to 59 with serum cholesterol levels above 265 mg/dl and no previous history of heart disease. It is not clear to what extent these findings can be extrapolated to females and other segments of the hypercholesterolemic population.

Two controlled clinical trials have examined the effects of cholestyramine monotherapy upon coronary atherosclerotic lesions using coronary arteriography. In the NHLBI Type II Coronary Intervention Trial[2], 116 patients (80% male) with coronary artery disease (CAD) documented by arteriography were randomized to cholestyramine resin or placebo for five years of treatment. Final study arteriography revealed progression of coronary artery disease in 49% of placebo patients compared to 32% of the cholestyramine resin group ($p<0.05$), a 35% reduction of disease progression with cholestyramine resin treatment.

In the St. Thomas Atherosclerosis Regression Study (STARS)[3], 90 hypercholesterolemic men with CAD were randomized to three blinded treatments: usual care, lipid-lowering diet, and lipid-lowering diet plus cholestyramine resin. After 36 months, follow-up coronary arteriography revealed progression of disease in 46% of usual care patients, 15% of patients on lipid-lowering diet and 12% of those receiving diet plus cholestyramine resin ($p<0.02$). The mean absolute width of coronary segments decreased in the usual care group, increased slightly (0.003 mm) in the diet group and increased by 0.103 mm in the diet plus cholestyramine group ($p<0.05$). Thus, in these randomized controlled clinical trials using coronary arteriography, cholestyramine resin monotherapy has demonstrated to slow progression and promote regression of atherosclerotic lesions in the coronary arteries of patients with or at risk for coronary artery disease.

The effect of intensive lipid-lowering therapy on coronary atherosclerosis has been assessed by arteriography in hyperlipidemic patients. In these randomized, controlled clinical trials, patients were treated for two to four years by either conventional measures (diet, placebo, or in some cases low dose resin), or intensive combination therapy using diet plus colestipol (an anion exchange resin with a mechanism of action and an effect on serum lipids similar to that of Cholestyramine for Oral Suspension) plus either nicotinic acid or lovastatin. When compared to conventional measures, intensive lipid-lowering combination therapy significantly reduced the frequency of progression and increased the frequency of regression of coronary atherosclerotic lesions in patients with or at risk for coronary artery disease.

INDICATIONS AND USAGE

1) Cholestyramine for Oral Suspension, USP is indicated as adjunctive therapy to diet for the

rate, and risk of progression, when compared to conventional measures, intensive lipid-lowering combination therapy significantly reduced the frequency of progression and increased the frequency of regression of coronary atherosclerotic lesions in patients with or at risk for coronary artery disease.

INDICATIONS AND USAGE

1) Cholestyramine for Oral Suspension, USP is indicated as adjunctive therapy to diet for the reduction of elevated serum cholesterol in patients with primary hypercholesterolemia (elevated low density lipoprotein [LDL] cholesterol) who do not respond adequately to diet. Cholestyramine resin may be useful to lower LDL cholesterol in patients who also have hypertriglyceridemia, but it is not indicated where hypertriglyceridemia is the abnormality of most concern.

Therapy with lipid-altering agents should be a component of multiple risk factor intervention in those individuals at significantly increased risk for atherosclerotic vascular disease due to hypercholesterolemia. Treatment should begin and continue with dietary therapy specific for the type of hyperlipoproteinemia determined prior to initiation of drug therapy. Excess body weight may be an important factor and caloric restriction for weight normalization should be addressed prior to drug therapy in the overweight.

Prior to initiating therapy with cholestyramine resin, secondary causes of hypercholesterolemia (e.g., poorly controlled diabetes mellitus, hypothyroidism, nephrotic syndrome, dysproteinemias, obstructive liver disease, other drug therapy, alcoholism), should be excluded, and a lipid profile performed to assess Total cholesterol, HDL-C, and triglycerides (TG). For individuals with TG less than 400 mg/dl (<4.5 mmol/L), LDL-C can be estimated using the following equation:

LDL-C = Total cholesterol - [(TG/5) + HDL-C]

For TG levels > 400 mg/dl, this equation is less accurate and LDL-C concentrations should be determined by ultracentrifugation. In hypertriglyceridemic patients, LDL-C may be low or normal despite elevated Total-C. In such cases cholestyramine resin may not be indicated.

Serum cholesterol and triglyceride levels should be determined periodically based on NCEP guidelines to confirm initial and adequate long-term response. A favorable trend in cholesterol reduction should occur during the first month of cholestyramine resin therapy. The therapy should be continued to sustain cholesterol reduction. If adequate cholesterol reduction is not attained, increasing the dosage of cholestyramine resin or adding other lipid-lowering agents in combination with cholestyramine resin should be considered.

Since the goal of treatment is to lower LDL-C, the NCEP[4] recommends that LDL-C levels be used to initiate and assess treatment response. If LDL-C levels are not available then Total-C alone may be used to monitor long-term therapy. A lipoprotein analysis (including LDL-C determination) should be carried out once a year. The NCEP treatment guidelines are summarized below.

		LDL Cholesterol mg/dl (mmol/L)	
Coronary Atherosclerotic Disease*	Two or More Other Risk Factors**	Initiation Level	Goal
NO	NO	≥190 (≥4.9)	160 (<4.1)
NO	YES	≥160 (≥4.1)	<130 (<3.4)
YES	YES or NO	≥130 (≥3.4)	≤100 (≤2.6)

*Coronary heart disease or peripheral vascular disease (including symptomatic carotid artery disease)

[illegible]	[illegible]	≥130 (≥3.4)	≤100 (≤2.6)

*Coronary heart disease or peripheral vascular disease (including symptomatic carotid artery disease).

**Other risk factors for coronary heart disease (CHD) include: age (males: ≥45 years, females: ≥55 years or premature menopause without estrogen replacement therapy); family history of premature CHD; current cigarette smoking; hypertension; confirmed HDL-C <35 mg/dl (<0.91 mmol/L); and diabetes mellitus. Subtract one risk factor if HDL-C is ≥60 mg/dl (≥1.6 mmol/L).

Cholestyramine resin monotherapy has been demonstrated to retard the rate of progression[11] and increase the rate of regression[3] of coronary atherosclerosis. In addition, in the LRC-CPPT trial, cholestyramine resin therapy reduced the combined rate of coronary heart disease death and non-fatal MI.

2) Cholestyramine for Oral Suspension, USP is indicated for the relief of pruritus associated with partial biliary obstruction. Cholestyramine for Oral Suspension, USP has been shown to have a variable effect on serum cholesterol in these patients. Patients with primary biliary cirrhosis may exhibit an elevated cholesterol as part of their disease.

CONTRAINDICATIONS

Cholestyramine resin, USP is contraindicated in patients with complete biliary obstruction where bile is not secreted into the intestine and in those individuals who have shown hypersensitivity to any of its components.

PRECAUTIONS

General

Chronic use of cholestyramine resin, USP may be associated with increased bleeding tendency to hypoprothrombinemia associated with Vitamin K deficiency. This will usually respond promptly to parenteral Vitamin K1 and recurrences can be prevented by oral administration of Vitamin K1. Reduction of serum or red cell folate has been reported over long term administration of cholestyramine resin, USP. Supplementation with folic acid should be considered in these cases.

There is a possibility that prolonged use of cholestyramine resin, USP, since it is a chloride form of anion exchange resin, may produce hyperchloremic acidosis. This would especially be true in younger and smaller patients where the relative dosage may be higher. Caution should also be exercised in patients with renal insufficiency or volume depletion, and in patients receiving concomitant spironolactone.

Cholestyramine resin, USP may produce or worsen pre-existing constipation. The dosage should be increased gradually in patients to minimize the risk of developing fecal impaction. In patients with pre-existing constipation, the starting dose should be 1 packet or 1 scoop once daily for 5 to 7 days, increasing to twice daily with monitoring of constipation and of serum lipoproteins, at least twice, 4 to 6 weeks apart. Increased fluid intake and fiber intake should be encouraged to alleviate constipation and a stool softener may occasionally be indicated. If the initial dose is well tolerated, the dose may be increased as needed by one dose/day (at monthly intervals) with periodic monitoring of serum lipoproteins.

If constipation worsens or the desired therapeutic response is not achieved at one to six doses/day, combination therapy or alternate therapy should be considered. Particular effort should be made to avoid constipation in patients with sympto-

mainc coronary artery disease. Constipation associated with cholestyramine resin may aggravate hemorrhoids.

Information for Patients

Inform your physician if you are pregnant or plan to become pregnant or are breastfeeding. Drink plenty of fluids and mix each 9-gram dose of Cholestyramine for Oral Suspension, USP in at least 2 to 6 ounces of fluid before taking. Sipping or holding the resin suspension in the mouth for prolonged periods may lead to changes in the surface of the teeth resulting in discoloration, erosion of enamel or decay; good oral hygiene should be maintained.

Laboratory Tests

Serum cholesterol levels should be determined frequently during the first few months of therapy and periodically thereafter. Serum triglyceride levels should be measured periodically to detect whether significant changes have occurred.

The LRC-CPPT showed a dose-related increase in serum triglycerides of 10.7%-17.1% in the cholestyramine-treated group, compared with an increase of 7.9%-11.7% in the placebo group. Based on the mean values and adjusting for the placebo group, the cholestyramine-treated group showed an increase of 5% over pre-entry levels the first year of the study and an increase of 4.3% the seventh year.

Drug Interactions

Cholestyramine resin, USP may delay or reduce the absorption of concomitant oral medication such as phenylbutazone, warfarin, thiazide diuretics (acidic), or propranolol (basic), as well as tetracycline, penicillin G, phenobarbital, thyroid and thyroxine preparations, estrogens and progestins, and digitalis. Interference with the absorption of oral phosphate supplements has been observed with another positively charged bile acid sequestrant. Cholestyramine resin may interfere with the pharmacokinetics of drugs that undergo enterohepatic circulation. The discontinuance of cholestyramine resin, USP could pose a hazard to health if a potentially toxic drug such as digitalis has been titrated to a maintenance level while the patient was taking cholestyramine resin, USP.

Because cholestyramine binds bile acids, cholestyramine resin, USP may interfere with normal fat digestion and absorption of fat-soluble vitamins such as A, D, E and K. When cholestyramine resin, USP is given for long periods of time, concomitant supplementation with water-miscible (or parenteral) forms of fat-soluble vitamins should be considered.

SINCE **CHOLESTYRAMINE RESIN, USP** MAY BIND OTHER DRUGS GIVEN CONCURRENTLY, IT IS RECOMMENDED THAT PATIENTS SHOULD TAKE OTHER DRUGS AT LEAST ONE HOUR BEFORE OR 4 TO 6 HOURS AFTER **CHOLESTYRAMINE RESIN, USP** (OR AT AS GREAT AN INTERVAL AS POSSIBLE) TO AVOID IMPEDING THEIR ABSORPTION.

Carcinogenesis, Mutagenesis, Impairment of Fertility

In studies conducted in rats in which cholestyramine resin was used as a tool to investigate the role of various intestinal factors, such as fat, bile salts and microbial flora, in the development of intestinal tumors induced by potent carcinogens, the incidence of such tumors was observed to be greater in cholestyramine resin-treated rats than in control rats.

The relevance of this laboratory observation from studies in rats to the clinical use of cholestyramine resin, USP is not known. In the LRC-CPPT study referred to above, the total incidence of fatal and nonfatal neoplasms was similar in both treatment groups. When the many different categories of tumors are examined, various alimentary system can-

resin, USP may bind other drugs given concurrently. It is recommended that patients should take other drugs at least one hour before or 4 to 6 hours after cholestyramine resin, USP (or at as great an interval as possible) to avoid impeding their absorption.

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The relevance of this laboratory observation from studies in rats to the clinical use of cholestyramine resin, USP is not known. In the LRC-CPPT study referred to above, the total incidence of fatal and nonfatal neoplasms was similar in both treatment groups. When the many different categories of tumors are examined, various alimentary system cancers were somewhat more prevalent in the cholestyramine group. The small numbers and the multiple categories prevent conclusions from being drawn. However, in view of the fact that cholestyramine resin is confined to the GI tract and not absorbed, and in light of the animal experiments referred to above, a six-year post-trial follow-up analysis of the LRC-CPPT patient population has been completed (a total of 13.4 years of in-trial plus post-trial follow-up) and revealed no significant difference in the incidence of cause-specific mortality or cancer morbidity between cholestyramine and placebo treated patients.

Pregnancy: Teratogenic Effects. Pregnancy Category C
Since cholestyramine resin, USP is not absorbed systemically, it is not expected to cause fetal harm when administered during pregnancy in recommended dosages. There are, however, no adequate and well controlled studies in pregnant women, and the known interference with absorption of fat-soluble vitamins may be detrimental even in the presence of supplementation.

Nursing Mothers
Caution should be exercised when cholestyramine resin, USP is administered to a nursing mother. The possible lack of proper vitamin absorption described in the "Pregnancy" section may have an effect on nursing infants.

Pediatric Use
As experience in the pediatric population is limited, a practical dosage schedule has not been established.

In calculating pediatric dosages, 4.4 mg of anhydrous cholestyramine resin are contained in 100 mg of cholestyramine for oral suspension, USP.

The effects of long-term drug administration, as well as its effect in maintaining lowered cholesterol levels in pediatric patients, are unknown.

ADVERSE REACTIONS
The most common adverse reaction is constipation. When used as a cholesterol-lowering agent predisposing factors for most complaints of constipation are high dose and increased age (more than 60 years old). Most instances of constipation are mild, transient, and controlled with conventional therapy. Some patients require a temporary decrease in dosage or discontinuation of therapy.

Less Frequent Adverse Reactions: Abdominal discomfort and/or pain, flatulence, nausea, vomiting, diarrhea, eructation, anorexia, and steatorrhea, bleeding tendencies due to hypoprothrombinemia (Vitamin K deficiency) as well as Vitamin A (one case of night blindness reported) and D deficiencies, hyperchloremic acidosis in chil-

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Occasional calcified material has been observed in the biliary tree, including calcification of the gallbladder, in patients to whom cholestyramine resin has been given. However, this may be a manifestation of the liver disease and not drug related.

One patient experienced biliary colic on each of three occasions on which he took a cholestyramine for oral suspension product. One patient diagnosed as acute abdominal symptom complex was found to have a "pasty mass" in the transverse colon on x-ray.

Other events (not necessarily drug related) reported in patients taking cholestyramine resin, USP include:

Gastrointestinal—GI-rectal bleeding, black stools, hemorrhoidal bleeding, bleeding from known duodenal ulcer, dysphagia, hiccups, ulcer attack, sour taste, pancreatitis, rectal pain, diverticulitis.

Laboratory test changes— Liver function abnormalities.

Hematologic—Prolonged prothrombin time, ecchymosis, anemia.

Hypersensitivity—Urticaria, asthma, wheezing, shortness of breath.

Musculoskeletal—Backache, muscle and joint pains, arthritis.

Neurologic—Headache, anxiety, vertigo, dizziness, fatigue, tinnitus, syncope, drowsiness, femoral nerve pain, paresthesia.

Eye—Uveitis.

Renal—Hematuria, dysuria, burnt odor to urine, diuresis.

Miscellaneous—Weight loss, weight gain, increased libido, swollen glands, edema, dental caries, erosion of tooth enamel, tooth discoloration.

OVERDOSAGE

Overdosage with cholestyramine resin, USP has been reported in a patient taking 150% of the maximum recommended daily dosage for a period of several weeks. No ill effects were reported. Should an overdosage occur, the chief potential harm would be obstruction of the gastrointestinal tract. The location of such potential obstruction, the degree of obstruction, and the presence or absence of normal gut motility would determine treatment.

DOSAGE AND ADMINISTRATION

The recommended starting adult dose for cholestyramine for oral suspension, USP is one packet or one level scoopful (9 grams of cholestyramine for oral suspension, USP contains 4 grams of anhydrous cholestyramine resin) once or twice a day. The recommended maintenance dose for cholestyramine for oral suspension USP is 2 to 4 packets or

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Cholestyramine for Oral Suspension should not be taken in its dry form. Always mix cholestyramine resin, USP with water or other fluids before ingesting. See Preparation instructions.

Concomitant Therapy

Preliminary evidence suggests that the lipid-lowering effects of cholestyramine on total and LDL-cholesterol are enhanced when combined with a HMG-CoA reductase inhibitor, e.g., pravastatin, lovastatin, simvastatin and fluvastatin. Additive effects on LDL-cholesterol are also seen with combined nicotinic acid/cholestyramine therapy. See the Drug Interactions subsection of the PRECAUTIONS section for recommendations on administering concomitant therapy.

Preparation

The color of cholestyramine resin, USP may vary somewhat from batch to batch but this variation does not affect the performance of the product. Place the contents of one single-dose packet or one level scoopful of cholestyramine resin, USP in a glass or cup. Add at least 2 to 6 ounces of water or the beverage of your choice. Stir to a uniform consistency.

Cholestyramine resin, USP may also be mixed with highly fluid soups or pulpy fruits with a high moisture content such as applesauce or crushed pineapple.

HOW SUPPLIED

Cholestyramine for oral suspension, USP is available in cartons of sixty 9-gram packets and in cans containing 378 grams. Nine grams of cholestyramine for oral suspension, USP contain 4 grams of anhydrous cholestyramine resin. Store between 15°C and 30°C.

NDC 0172-2830-90
Carton of 60 packets
NDC 0172-2830-36
Cans, 378 g

REFERENCES

1. The Lipid Research Clinics Coronary Primary Prevention Trial Results. (I) Reduction in Incidence of Coronary Heart Disease. (II) The Relationship of Reduction in Incidence of Coronary Heart Disease to Cholesterol Lowering. JAMA 1984; 251:351-374.

2. Brensike JF, Levy RI, Kelsey SF, et al. Effects of therapy with cholestyramine on progression of coronary arteriosclerosis: results of the NHLBI type II coronary intervention study. Circulation 1984;69:313-24.

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HOW SUPPLIED
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NDC 0172-2830-60
Carton of 60 packets
NDC 0172-2830-36
Cans, 378 g

REFERENCES

1. The Lipid Research Clinics Coronary Primary Prevention Trial Results: (I) Reduction in Incidence of Coronary Heart Disease; (II) The Relationship of Reduction in Incidence of Coronary Heart Disease to Cholesterol Lowering. JAMA 1984; 251:351-374.

2. Brensike JF, Levy RI, Kelsey SF, et al. Effects of therapy with cholestyramine on progression of coronary arteriosclerosis: results of the NHLBI type II coronary intervention study. Circulation 1984;69:313-24.

3. Watts, GF, Lewis B, Brunt JNH, Lewis ES, et al. Effects on coronary artery disease of lipid-lowering diet, or diet plus cholestyramine, in the St. Thomas Atherosclerosis Regression Study (STARS). Lancet 1992;339:563-69.

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May 1997

Manufactured by: 0172

Zenith [illegible]

Ft. Lauderdale, FL 33309
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I001396
Rev. 9705

Single Dose

Zenith Goldline

NDC 0172-2830-33

CHOLESTYRAMINE

FOR ORAL SUSPENSION, USP

CAUTION: FEDERAL LAW PROHIBITS DISPENSING WITHOUT PRESCRIPTION.

Usual Dosage: See Package Insert.

Store between 15° and 30°C (59° and 86°F).

Preparation: Place the contents of one packet in a glass or cup. Add at least 2 to 6 ounces of water or the beverage of your choice. Stir to a uniform consistency.

Keep this and all medication out of the reach of children. This package is not child-resistant.

Each packet contains 4 grams of anhydrous cholestyramine in 9 grams of Cholestyramine For Oral Suspension, USP.

This product contains sucrose.

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ZENITH GOLDLINE PHARMACEUTICALS, INC.
FT LAUDERDALE, FL 33309
X001393 Rev.9704

APPROVED

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Zenith Goldline

NDC 0172-2830-36

MEASURED DOSES
CONTENTS 378 g (168 g ANHYDROUS CHOLESTYRAMINE)

CHOLESTYRAMINE FOR ORAL SUSPENSION, USP

4 grams cholestyramine resin, USP, per scoopful*

This product contains sucrose.

SCOOP ENCLOSED.
Scoop provided is not interchangeable with scoops for other products.

Usual Dosage: See package insert.
Store between 15° and 30°C (59° and 86°F).

CAUTION: Federal law prohibits dispensing without prescription.

Preparation

1. A scoop is enclosed to help you measure accurately. Do not force or pack the powder into the scoop.
2. Place one level scoopful of CHOLESTYRAMINE FOR ORAL SUSPENSION, USP in a glass or cup.
3. Add 2 to 6 ounces of water or the beverage of your choice and stir vigorously.
4. Add at least 2-4 more ounces of beverage to suit individual taste and stir vigorously again.
5. The slightly textured CHOLESTYRAMINE FOR ORAL SUSPENSION, USP is now ready to drink.

Always mix CHOLESTYRAMINE FOR ORAL SUSPENSION, USP with water, or the beverage of your choice, or other highly fluid foods or fruits before using.

Keep this and all medication out of the reach of children. This package is not child-resistant.

Always replace plastic lid after using.

Usual Dosage: See package insert for dosage information.

*Each level scoopful (9 grams) of CHOLESTYRAMINE FOR ORAL SUSPENSION, USP contains 4 grams of cholestyramine resin, USP.

NDC 0172-2830-36
ZENITH GOLDLINE
PHARMACEUTICALS, INC
FT. LAUDERDALE, FL 333

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Rev.9704

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